Continuing Review Submissions

**SKIP TO PAGE 10 IF THIS STUDY HAS BEEN PREVIOUSLY APPROVED/RENEWED IN MYRESEARCH**

** You should see all of your imported studies in the All Submissions section of your IRB page (see below for instructions for searches in myResearch). If you do not see one of your studies, please review the following points to obtain access to the study shell in myResearch:

1) All studies should be available to the PI. If you are the approved PI in IRBNet but you do not see one of your studies, send an email with the IRBNet ID number to OVPR_myresearchIRB@stonybrook.edu for assistance.

2) If you are not the PI and you do not see one of your studies, first contact the PI to confirm that the study is not already available in myResearch.
   a. If you do not have access but the study is available to the PI, it means that your name was not included in the imported data. You must ask the PI to assign you as the Primary Contact. This requires simply accessing the study and clicking “Assign Primary Contact” in the left navigation area to select your name. This will give you immediate access to the study in myResearch and you will receive all notifications related to this study. Note: The primary contact can be changed as often as necessary by any study team member.
   b. If the PI also does not have access to the study, send an email with the IRBNet ID number to OVPR_myresearchIRB@stonybrook.edu for assistance.

** Do not follow these instructions for studies with an external IRB as the IRB of record. Refer to the “Create an External IRB Submission” manual.

1) Click on the IRB tab
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2) Use one of the various filters to search for your study using the IRBNet ID number (no hyphen, no package number). Search under the All Submissions tab. Notice that you can also filter by ID as well as the study name listed in IRBNet or the PI first/last name.

3) Select the study title. This will route you to the study’s main workspace with several actions available to you on the left side of the screen. Select Create Modification/CR.

Important Note: If you select any option other than Continuing Review and Modification and then select Continue, the system will not allow you to update this selection. You will need to select Discard (on the left navigation area of the main workspace) and start again.
4) You will be asked to select the scope of the modification. Select **BOTH** options. **This will allow you to review the automatically imported information in your application and add documents for review.** (See the Continuing Review Submission Requirements Checklist.)
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5) Complete the Continuing Review/Study Closure Information page.

“Since Last Approval” refers to the number of subjects enrolled in your study since the last IRB approval. This may be since the start of the study (if it is the first renewal). If this is not the first renewal, you will enter the number of subjects enrolled since reported at the time of the last renewal.

Total at this site: Number of subjects enrolled by SBU investigators (by written consent or otherwise)
Total at all sites everywhere that are conducting this protocol: For a single-site study, this is the same as the total “at this site.”
Total number of subjects approved study-wide: This is the number of subjects that you are approved to enroll for this study, not necessarily the number enrolled so far. Refer to the approved protocol. If you are enrolled for open-ended enrollment, indicate 999999.

2. Research milestones: (Select all that apply. If enrollment of subjects is ongoing, skip this section.)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

Important: If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

For question 2, check all that apply to this study. If enrollment of subjects will continue in the future, do not select any boxes. If the study involves collection of data only (e.g. chart reviews) and reviews will continue in the future, do not select any boxes. Selecting the first four research milestones will result in a request to confirm that the study should be permanently closed (ending IRB oversight).
For question 3, check the box next to each item to confirm that is true as of the last IRB approval. For example, if no subject experience unexpected harm and no anticipated adverse events took place with greater frequency or severity than expected, these boxes should be checked. If there are any boxes that you cannot check, you must provide appropriate documentation for review. For example, if you do not check that there are no data safety monitoring reports as of the last IRB approval, you are indicating that there is such a report and it must be uploaded for question 4.

Only upload documents as applicable to your study. No documents are required for question 5 unless there was enrollment in the most recent approval period and the study was approved with written consent. A redacted inclusion/exclusion criteria checklist is not required if no such document was previously approved. If the study involves written parent permission and written assent, upload the redacted versions of both forms for the last subject enrolled in the most recent approval period. Note: Only subject identifiers (e.g. name, initials, signature) should be redacted.

Select Continue once the page is complete.
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6) Complete the Modification Information page. Confirm that the selections for study enrollment status are consistent with those indicated on the previous page. If you are making any modifications to the study (previously documents, procedures, study team), **summarize each modification and provide a clear rationale for each modification in the text box.**

**Modification Information**

1. **Study enrollment status:**
   - No subjects have been enrolled to date
   - Subjects are currently enrolled
   - Study is permanently closed to enrollment
   - All subjects have completed all study-related interventions
   - Collection of private identifiable information is complete

2. **Notification of subjects:** (check all that apply; N/A if requesting a subject-specific protocol exception)
   - Current subjects will be notified of these changes
   - Former subjects will be notified of these changes

*Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.*

3. **Summarize the modifications:**

![Summarize the modifications]

7) Once the page is complete, select **Continue** to review each page of the application for accuracy and upload documents as needed. (See the Continuing Review checklist in the **For Investigators** library in myResearch or navigate to [https://research.stonybrook.edu/myResearch-IRB#checklists-(irb)](https://research.stonybrook.edu/myResearch-IRB#checklists-(irb)) for the Continuing Review Submission checklist.)

Reminders related to the various pages:

- ![?] ![?] Click on these question mark icons for additional guidance in select sections of the SmartForm.
- Each response must be reviewed carefully for accuracy. There are many fields (e.g. Brief Lay Description) that could not be populated with imported data. It is the PI’s responsibility to ensure that all requested information and documents are revised/added as necessary.
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- **Attach the protocol:** This refers to the most recently approved protocol document. Do not complete the new protocol template provided in this section as that document is for new studies submitted in myResearch only. If there are any proposed changes since last approved, indicate the tracked changes and be sure to return to the Summarize the Modifications section of the SmartForm to add the summary of changes with an appropriate rationale.

- **Funding Sources:** You are required to list external funding sources only. The funding sources available in myResearch IRB are linked to the list of sources that have been previously routed through the Grants module. If you would like to request the addition of a particular funding source, you must submit the request at the following webpage: [https://research.stonybrook.edu/request-add-sponsor](https://research.stonybrook.edu/request-add-sponsor). All required fields must be completed before it can be reviewed. If you do not see the funding source available by the end of the next business day, you can contact IT directly at ovpr-it@stonybrook.edu to check the status.

- On the **Study Team Members** page, confirm that all individuals listed have up-to-date training. If you hover over the color-coded boxes under the IRB Training column you will see when the training will expire. Note: If you do not see any boxes for human subjects training, contact that study team member to ensure that the appropriate level of human subjects training is completed and their CITI account is linked to their NetID. If training is up-to-date but the color-coded boxes do not appear in myResearch, request that the person completes the NetID/CITI account linking process by following these instructions: [https://research.stonybrook.edu/human-subjects#linking-your-sbu-netid-to-citi-](https://research.stonybrook.edu/human-subjects#linking-your-sbu-netid-to-citi-). **All research study personnel must have up-to-date training prior to IRB approval.**

- **Consent Forms:** As in the case of the protocol, you are not creating your consent/assent/permission forms using the templates. Upload your most recently approved Word doc version(s) to be re-approved. This should be a clean version (all previously approved tracked changes, highlighting, or comments removed, no watermarks, etc) unless there are new proposed changes. Proposed changes should be indicated using the Tracked Changes feature in Word. Again, be sure to return to the Summarize the Modifications section of the SmartForm to add the summary of changes with an appropriate rationale. Note: Even if previously approved for a consent waiver (waiver of informed consent or waiver of documentation), the Supplemental Form G must be completed and uploaded in the Consent Forms section. The template is available in that section.

- **Recruitment Materials:** Be sure to upload all documents that you intend to continue using even if you previously uploaded these documents in IRBNet (e.g. questionnaires, assessments, announcements, flyers, advertisements, recruitment emails, screening materials).
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- **Other Attachments**: Upload any remaining documentation that may be necessary for this study (e.g. documentation of lead site/collaborating site ongoing IRB approvals, Application to Conduct Research Activities at Stony Brook University Hospital if the study involves SBU hospital patients/resources/facilities).

- Confirm that clean versions of documents to be stamped are uploaded. Do not upload any stamped versions of documents (e.g. stamped flyers) as they cannot be re-stamped in the system.

- Be sure to click Save on the top/bottom of the page once you complete each page to ensure that you do not lose your work.

8) Once you believe the application is ready to submit, select at the top/bottom of the page to see a list of required sections that have not been completed. This will check for completeness, not verify accuracy of responses.

9) You will reach a Final Page after the Local Site Documents page. Be sure to read this page carefully to ensure that you have requested required ancillary reviews prior to submitting your application. **NOTE: Department Chair approval via ancillary review must be obtained before submission.** Any continuing review submissions missing documentation of this review will result in a Clarification or submission withdrawal.

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You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click Finish to exit the form.
2. On the main page, Click on "Manage Ancillary Reviews", click on "Add" and select your department chair/dep’t review.com
   - Review type: 'Department Chair (scientific merit, resources)'
   - Is a response required?: YES

**Note:** Do not submit this IRB submission without the PI’s Department Chair’s documented approval. The PI and study staff the Principal Investigator must return to the submission and submit it to the IRB.

Select these additional individuals, as applicable, if your research activity involves the facilities, patients, and/or services clinics located at Riverhead, Southold, Plainview, or Medford:

**Note:** You must not commence with your study until all these applicable approvals are documented in myResearch:

- **Select Rhona Veidner (Chernoff) and Regina Rigoroce and John Shen**
  - Review type: Hospital Budget
  - Is a response required? YES (only one of these individuals must approve the submission before you commence

- **Select the Chief Medical Officer**, if your study involves an investigational device, or an FDA-approved device being s
  - Review Type: Other
  - Is a response required? YES

- **Select Eric Spitzer** if your study involves Pathology/Laboratory Services
  - Review Type: Pathology
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10) Click Finish to exit the page and select Manage Ancillary Reviews to request all necessary reviews. Refer to the instructions on the Final Page to confirm how to answer the questions on the Manage Ancillary Reviews page.

11) The PI and study team will receive an email notification when the Department Chair/Designated Signatory has submitted a review and accepted/approved the submission. This notification will also appear in the History section (see previous image).

12) Once Department Chair/Designated Signatory approval is confirmed, the Principal Investigator can click Submit (see previous image) and agree to the Principal Investigator certification by clicking OK.
Continuing Review Submissions

Instructions for studies that were previously approved/renewed in myResearch:

1) Click on the IRB tab

2) Use one of the various filters to search for your study using the IRBNet ID number (no hyphen, no package number). Search under the All Submissions tab. Notice that you can also filter by ID as well as the study name listed in IRBNet or the PI first/last name.
Continuing Review Submissions

3) If you do not have any proposed changes to the study to submit at this time, you can choose the **Continuing Review option only**. Keep in mind that this will give you access to the Continuing Review/Study Closure Information page only. You will not be able to modify any previously approved documents, make changes to the study team, or update any other sections of the most recently approved application SmartForm. If you are making any changes (adding a study team member, modifying the protocol or consent form, etc), you must choose **Modification and Continuing Review**.

*For those requiring the Modification and Continuing Review option, choose the scopes appropriately based on what you will need to access. Selecting only the Study Team Members Information page will give you access to the Continuing Review/Study Closure Information page, Modification Information page, and the **Study Team Members page only**. Selecting both scopes (Study Team Members Information and Other Parts of the Study) will give you access to all of these pages as well as the remainder of the original application SmartForm (e.g. all documents, study description, title/PI name selection).*

4) If you choose **Continuing Review only**, see pages 4 and 5 of this manual for guidance on completing the Continuing Review/Study Closure Information page. If you must choose **Modification and Continuing Review** for this study, see pages 4 through 6 of this manual for guidance on completing the Continuing Review/Study Closure Information page and the Modification Information page.

5) Review each page of the application SmartForm until you reach the Final Page. Confirm that you have replaced/removed documents that no longer require approval. For example, if you are making changes to a previously approved consent form, you should update the version in the system rather than simply adding the additional document. There should be only one version of a given document to reduce clutter in the system. Changes should be indicated with
Continuing Review Submissions

Tracked Changes. Please do not use highlighting to indicate changes in documents that need to be stamped for use (e.g. advertisements, consent forms, recruitment scripts).

6) Once you believe the application is ready to submit, select at the top/bottom of the page to see a list of required sections that have not been completed. This will check for completeness, not verify accuracy of responses.

7) You will reach a Final Page after the Local Site Documents page. Be sure to read this page carefully to ensure that you have requested required ancillary reviews prior to submitting your application. Given that this study was previously approved in myResearch, the study was presumably already shared with required ancillary reviewers (e.g. University Hospital reviewers) and their approval has already been received. The PI must confirm that all necessary ancillary reviews have been obtained. **NOTE: Department Chair approval via ancillary review must be obtained before submission. Any continuing review submissions missing documentation of this review will result in a Clarification or submission withdrawal.**

### Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click Finish to exit the form.
2. On the main page, Click on “Manage Ancillary Reviews”, click on “Add” and select your department chair/dep’t review con
   
   - Review type: ‘Department Chair (scientific merit, resources)’
   - Is a response required?: YES

   **Note: Do not submit this IRB submission without the PI’s Department Chair’s documented approval. The PI and study staff the Principal investigator must return to the submission and submit it to the IRB.**

   Select these additional individuals, as applicable, if your research activity involves the facilities, patients, and or/services/clinics located at Riverhead, Southold, Plainview, or Medford:

   **Note: You must not commence with your study until all these applicable approvals are documented in myResearch:**

   - Select Rhona Vainder (Chernoff) and Regina Rigoroso and John Shen
     
     Review type: Hospital Budget
     
     Is a response required? YES (only one of these individuals must approve the submission before you commence

   - Select the Chief Medical Officer, if your study involves an investigational device, or an FDA-approved device being s
     
     Review Type: Other
     
     Is a response required? YES

   - Select Eric Spitzer if your study involves Pathology/Laboratory Services
     
     Review Type: Pathology
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8) Click Finish to exit the page and select Manage Ancillary Reviews to request all necessary reviews. Refer to the instructions on the Final Page to confirm how to answer the questions on the Manage Ancillary Reviews page.

9) The PI and study team will receive an email notification when the Department Chair/Designated Signatory has submitted a review and accepted/approved the submission. This notification will also appear in the History section (see previous image).

10) Once Department Chair/Designated Signatory approval is confirmed, the Principal Investigator can click Submit (see previous image) and agree to the Principal Investigator certification by clicking OK.